

REMARKS

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

In the present Reply, claims 1, 3 and 5 have been amended. Also, claims 2 and 4 have been canceled without prejudice or disclaimer of the subject matter contained therein. In addition, claims 7-8 are added. Thus, claims 1, 3, 5 and 6-8 are pending in the present application.

No new matter has been added by way of these amendments, because each amendment is supported by the present specification. For example, the amendment to claim 1 has support in the subject matter of canceled claim 2 as well as in the present specification at pages 4, lines 23-25. The amendment to claim 3 has support in claim 4 and the specification at page 4, line 25. Finally, the amendment to claim 5 has support at page 5, lines 22-24 of the present specification.

No new matter has been added with claims 7-8 as these claims have support at least at page 2, lines 5-7 of the present specification.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims. Applicants note that the rejection under 35 U.S.C. § 103(a) is discussed first.

Issues under 35 U.S.C. § 103(a)

Claims 1-2 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kawashima *et al.* '856 (U.S. Patent No. 5,354,856) and Flickinger *et al.* (*Encyclopedia of Bioprocess Technology* (1999)) (see pages 3-5 of the Office Action). Applicants respectfully traverse and reconsideration is based on the following remarks. Overall, Applicants do not concede that a *prima facie* case of obviousness has been established.

The Present Invention

The present invention relates to a method of manufacturing crystalline maltitol, comprising supplying a maltitol aqueous solution having a high concentration to a kneader to knead and cool it, cooling the produced plastic lump to obtain a solidified product, and grinding this solidified product. The present invention more specifically relates to the following two embodiments.

(1) *First invention (crystallization by concentration difference between raw material maltitol aqueous solutions)*

A first maltitol aqueous solution is supplied (which is to be kneaded and cooled), and then a second maltitol aqueous solution having a higher solid content than that of the first maltitol aqueous solution is supplied, which is kneaded and cooled together with the first maltitol aqueous solution to manufacture crystalline maltitol (see pending claim 1 as presented herein).

(2) *Second invention (crystallization by concentration difference made by diluting a raw material with water)*

A maltitol aqueous solution is supplied (to be kneaded and cooled) and then water is added which is to be kneaded and cooled together with the maltitol aqueous solution to manufacture crystalline maltitol (see claim 3).

The Rejection in View of Kawashima et al. '856 and Flickinger et al.

As stated in pages 3-4 of the Office Action, the Examiner admits Kawashima et al. '856 fails to disclose the instantly claimed water addition(s) and/or the step of additional extrusion(s) after water addition. Thus, the Examiner cites Flickinger et al. (1999) to account for the deficient disclosure of the primary reference. However, Applicants respectfully submit that one of ordinary skill in the art would not combine such disclosures in an effort to achieve the present invention.

Japanese Patent Publication No. 7-14953, which is introduced as a previously known reference at page 1 of the present specification, corresponds to the cited Kawashima et al. '856 patent. As described in Applicants' specification, Kawashima et al. '856 discloses a method of manufacturing a maltitol-containing honey crystal by kneading and cooling a maltitol aqueous solution in the presence of a seed crystal. However, since the existence (addition) of a seed crystal is essential to the crystallization of maltitol in the Kawashima et al. '856 method, production efficiency is relatively lowered and an apparatus for adding the seed crystal is required thereby complicating the production process.

In contrast to Kawashima *et al.* '856, the present invention solves the above problems associated with the method of Kawashima *et al.* '856 and provides a method of manufacturing crystalline maltitol efficiently without adding a seed crystal.

Further, the existence (addition) of water is essential to the invention of Kawashima *et al.* '856. In contrast to this, the present invention is based on a new concept and technical idea that a maltitol aqueous solution is crystallized efficiently without the use of a seed crystal. Therefore, the invention of Kawashima *et al.* '856 and the present invention significantly differ from each other in concept and technical idea.

Regarding claim 1 (the first invention) as presented herein, the second maltitol aqueous solution is supplied in a liquid form, and it is evident that the seed crystal of Kawashima *et al.* '856 does not correspond to the instantly claimed second maltitol aqueous solution. Thus, the rejection of at least claim 1 is improper.

Regarding claim 3, (the second invention), the cited Flickinger *et al.* reference discloses an extruder having a water feed. This water feed is used to mold a product obtained by adding water to a food material and cooking it, and not used for crystallization. Flickinger *et al.* merely disclose an apparatus having a water feed, and fail to suggest a method of crystallizing a maltitol aqueous solution by adding water. And as mentioned, the primary reference of Kawashima *et al.* '856 is directed to cooling and kneading a maltitol aqueous solution in the presence of a seed crystal (it has been considered that a seed crystal is indispensable for the crystallization of maltitol), and thus Kawashima *et al.* '856 gives no guidance other than using a seed crystal for crystallization. Therefore, one of ordinary skill in the art would not have been motivated and/or reasonably expect to be successful in applying the invention of Flickinger *et al.*, which merely

disclose an extruder having a water feed, to the method of Kawashima *et al.* Even so, if water from Flickinger *et al.* is somehow added to the method of Kawashima *et al.*, water and a seed crystal must be added separately, thereby reducing production efficiency. In other words, there is still use of a seed crystal and thus the asserted combination of references is improper.

Thus, the rejection in view of Kawashima *et al.* '856 and Flickinger *et al.* has been overcome. A proper analysis under § 103(a) requires consideration of the four *Graham* factors of: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of secondary considerations (e.g., commercial success; unexpected results). 383 U.S. at 17, 148 USPQ at 467. Here, the Examiner has not appropriately resolved the *Graham* factors, including ascertaining the differences between the prior art and the claims that are at issue. For instance, as mentioned, the present invention utilizes a maltitol aqueous solution that is crystallized efficiently without the existence of a seed crystal. That is not the case with the cited Kawashima *et al.* '856 and Flickinger *et al.* references. Further, even when the disclosures are somehow combined (e.g., water is added to the method of Kawashima *et al.* '856), water and a seed crystal must be added separately, which reduces production efficiency. In other words, the requisite reasonable expectation of success and/or motivation for a *prima facie* case of obviousness are lacking.

Further, a claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. *See* M.P.E.P. §§ 2143.01 (see sections entitled "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For Its Intended Purpose" and "The Proposed Modification Cannot Change the

Principle of Operation of a Reference") and M.P.E.P. § 2145(III). Here, Kawashima *et al.* '856 requires seed crystals whereas the present invention does not. Thus, the Examiner's proposed modification would thus change the principle of operation of the primary reference and this rejection is improper for this additional reason.

In addition, Applicants note the last paragraph of page 4 of the Office Action, wherein Applicants respectfully traverse the Examiner's assertion of what is "optimal." The Examiner has not provided any technical or scientific evidence as to what ingredients/steps of the present invention are considered "optimal," and these comments by the Examiner are essentially a form of "Official Notice," which is improper, and is merely an attempt by the Examiner to manufacture "prior art" without providing any citation or evidence that any prior art has been uncovered. In this regard, the Examiner is respectfully requested to refer to *In re Zurko*, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001) (holding that general conclusions concerning what is "basic knowledge" or "common sense" to one of ordinary skill in the art without specifying factual findings and some concrete evidence in the record to support these findings will not support an obviousness rejection).

Thus, this rejection has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

Issues under 35 U.S.C. § 112, Second Paragraph

Claims 1-6 stand rejected under 35 U.S.C. § 112, second paragraph, for asserted lack of definiteness (see page 2 of the Office Action).

Also, claim 5 stands rejected under 35 U.S.C. § 112, second paragraph as stated on page 3 of the Office Action.

Applicants respectfully traverse, and reconsideration and withdrawal of these rejections are respectfully requested.

Claims 1-6

The Examiner has questioned how such a high solid content as claimed can be considered an aqueous solution. The solid content in the phrase “an aqueous solution has a solid content of 97.5 to 99.5 wt%” of the present claims refers to the content of the maltitol composition (containing a trace amount of another sugar such as sorbitol) other than water, and is expressed in this manner to distinguish it from water. This does not mean that the composition itself exists in a solid form.¹

Also, as described in paragraph [0021] of the publication corresponding to the specification of the present application, the maltitol aqueous solution supplied as a raw material is obtained by concentrating a maltitol aqueous solution having a solid content of 70% (water content of 30%) to a solid content of 97.5 to 99.5% (water content of 2.5 to 0.5%). Therefore, the maltitol aqueous solution containing a trace amount of water is expressed as an “aqueous solution.” In other words, the phrase “an aqueous solution has a solid content of 97.5 to 99.5 wt%” means that the solid is melted and mixed with a small amount of water in liquid form. Therefore, if a substance is a “solid substance” even though it contains 2.5 to 0.5 % of water, it is

¹ Solid matter is melted into a liquid form, which is made clearer by the recitation of the temperature being from 120 to 140°C.

not an “aqueous solution” as used in the present invention. Applicants note that the same disputed expression is seen in Kawashima *et al.* ‘856 (which is cited in the § 103(a) rejection discussed above) and is thus understood by one of ordinary skill in the art. Since the “seed crystal” in the cited Kawashima *et al.* ‘856 reference (see below) is obviously a solid crystal, it is not an “aqueous solution.”

Thus, a melted form of a solid containing water corresponds to an “aqueous solution” as used in the present invention (Applicants also note that the “seed crystal” of Kawashima *et al.* is not in a melted form).

Applicants also note that the temperature range of 120 to 140°C now appears in claims 1 and 3. Give the above explanation, Applicants respectfully submit that the disputed claim language is clear to one of skill in the art. The maltitol aqueous solution differs in state according to the solid content. Also, the maltitol aqueous solution having a solid content of 70 to 90% (first maltitol aqueous solution) is liquid at 90 to 120°C, and the maltitol aqueous solution having a solid content of 97.5 to 99.5% (second maltitol aqueous solution) is liquid at 120-140°C. The maltitol aqueous solution is always supplied in a liquid form.

Therefore, the present claim language fully complies with the provisions of 35 U.S.C. § 112, second paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim 5

As for claim 5, this rejection has been instantly overcome as the disputed claim language has been removed. Instead, the amount of water is limited is now recited.

Thus, this rejection has also been overcome. Reconsideration and withdrawal thereof are respectfully requested.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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